REMARKS

Claims 1-127 are pending.

Applicants elect Group I (claims 1-46, 55-111 and 115-116) in response to the Examiner's restriction requirement. Applicants traverse the requirement because a search and examination of all claims in the same patent application would not be an undue burden as shown by U.S. Patent Nos. 6,087,341 and 6,348,450 (see attached).

With regard to the other requirement, ADP-ribosylating exotoxins (e.g., cholera toxin) are elected as a specific adjuvant. Elected claims 1-46, 55-67, 72-111 and 115-116 read on the elected adjuvant.

The Examiner is urged to add new claims 117-127 to Group I.

The amendments are supported by the original disclosure and, thus, no new matter has been added. If the Examiner should disagree, however, he is respectfully requested to point out the challenged limitation with particularity in the next Action so support may be cited in response.

In particular, claims 1, 37-38 and 41-44 have been amended to be consistent with the elected subject matter. The title has been amended to better describe the subject matter of the elected claims. See support on page 1, lines 15-18, of the specification. Use of polynucleotide was described in Applicants' U.S. Patent No. 5,980,898 (filed July 17, 1998) on col. 14, lines 13-29, of the specification.

The new claims 117-127 are added to provoke an interference under 37 CFR §1.607 between this application and U.S. Patent No. 6,348,450 (copy attached) issued February 19, 2002. The latter appears to claim a priority claim of August 13, 1997, which is subsequent to Applicants' effective filing date.

New claims 117-127 represent copies of, inter alia, claims 1-3, 16-19, 24-29, 35-39, 44-47 and 52 of the patent. The differences in claim language are inconsequential modifications (e.g., organism instead of mammal; polynucleotide expressing antigen, adjuvant or both with an operably-linked regulatory region derived from a viral genome instead of DNA viral vector that encodes a gene of interest) so as to accommodate for differences between the disclosures of Applicants and the patent.

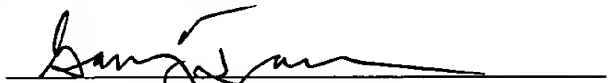
It is believed that an appropriate interference count would be patent claim 25 and/or Applicants' claim 117. If so, patent claims 1-52 and Applicants' claims 117-127 would be directed to the same invention.

The Examiner's consideration of the request to provoke an interference under 37 CFR §1.607 between this application and U.S. Patent No. 6,087,341 (see attached) is also earnestly solicited. See pages 6-7 of the Response dated July 10, 2001.

An early examination on the merits is respectfully requested. The Examiner is invited to contact the undersigned if any further information is required.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: 

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Attachments

APPENDIX
MARKED-UP VERSION TO SHOW CHANGES

IN THE TITLE

The title is amended as follows: GENETIC [SKIN-ACTIVE ADJUVANTS FOR TRANSCUTANEOUS] IMMUNIZATION BY EPICUTANEOUS APPLICATION

IN THE CLAIMS

The claims are amended as follows:

1. (2 x Amended) A method for transcutaneous immunization comprising:

(a) providing a formulation comprised of at least one antigen and at least one adjuvant, wherein said at least one antigen or said at least one adjuvant [antigen] is provided as at least one polynucleotide encoding said at least one antigen or said at least one adjuvant;

(b) applying said formulation epicutaneously to skin of an organism without penetrating past dermis of said skin; and

(c) inducing an antigen-specific immune response in said organism.

14. (Amended) A method of claim 1, wherein the antigen and the adjuvant are provided as separate components of the formulation.

37. (Amended) A method of claim 1, wherein the induced immune response recognizes at least one protein [carbohydrate] antigen of a bacterium [pathogen].

38. (Amended) A method of claim 1, wherein the induced immune response recognizes at least one protein [glycolipid] antigen of a virus [pathogen].

41. (Amended) A method of claim 1, wherein the antigen is provided as at least one polynucleotide encoding said antigen in whole cell form selected from the group consisting of live microbes, attenuated microbes, and inactivated microbes.

42. (Amended) A method of claim 1, wherein the antigen is provided as at least one polynucleotide encoding said antigen in a viral particle or virion form selected from the group consisting of live viruses, attenuated viruses, and inactivated viruses.

43. (Amended) A method of claim 1, wherein the antigen is provided as at least one polynucleotide encoding said antigen in a whole-cell form selected from the group consisting of live bacteria, attenuated bacteria, and inactivated bacteria.

44. (Amended) A method of claim 1, wherein the antigen is provided as at least one polynucleotide encoding said antigen in a cell-free form.

New claims 117-127 are added.